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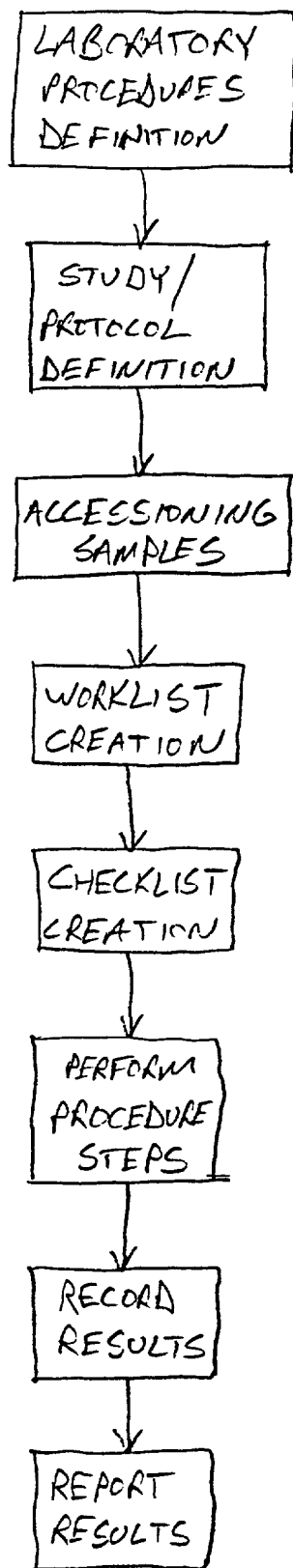


Fig 1

Clinical Study Definition

- Describes Sponsors & Investigators
- Declares Subject Attributes to Capture
- Associates Specific Lab Procedures with a Clinical Study
- Defines Genotype Results to Report

Study Protocol		Sponsor Study Number 632-001		Sponsor A CO., JOHN DOE, Ph.D.	
938-1008		Sample test		B CO., JANE SMITH	
PST		SS1		C CO., DAVID JONES	
Sponsor Protocol Title: Pharmacokinetic Evaluation of Orosol (oxybutylin chloride) and IR oxybutylin Administered Alone and in the Presence of Ketoconazole		Sponsor Study No: 198-005			
PPG1 Protocol Title: Genomic DNA isolation and molecular genotyping analysis of CYP2D6 "A", "B", "D", "E", "G", and "H" alleles		Study No: 632-001			
Procedures: DNA Isolation, 3 ml. whole blood, Purpure K2 SpectroMax DNA quantitation CYP2C9*3 CYP2C9*2 Ver. 7		Investigator: JOHN DOE, Ph.D.			
Subject Attributes: Subject Number Gender Birthdate Ethnicity		Final Storage Tube Range [1]			
Created 104/99 12:02		Modified 105/99 14:30		Define Results	
DNALIMS		DNALIMS		Delete	
				New	
				Modify	
				Cancel	
				Close	

FIG. 2

Accessioning

Clinical Sample Registration

- Provides Validation Checks for Accession & Tube ID's
- Accommodates Multiple Sample Tubes
- Enforces Controlled Subject Attribute Terms
- Supports Sample Workflow

Accessioning

Study No.	Accession No.	Sponsor Sample Tube ID	Sample Tube ID	Received Date	Location
632-001	A100123	BA10112	PS22156	09 OCT-1999	
632-001	A100124	BA10113	PS22157	09 OCT-1999	
632-001	A100125	BA10114	PS22158	09 OCT-1999	
632-001	A100126	BA10115	PS22159	09 OCT-1999	

PPGs Study No: [532001] Sponsor: [A.C.O. (JOHN DOE, Ph.D.)] Date Received: [09 Oct-1999] Sample Type: [EDTA Whole Blood]

Sponsor Sample Tube ID: [BA10115] Tube 1 [] Tube 2 [] Tube 3 [] Tube 4 []

PPGs Sample Tube ID: [PS22159] Tube 1 [] Tube 2 [] Tube 3 [] Tube 4 []

Sample Tube Volume: [] Sample Condition: [] Sample Attributes: []

Comments: []

Subject Information:

Subject Number: [15678] Gender: [M] Birthdate: [18 Sep-88] Ethnicity: [Black]

Buttons: [New] [Delete] [Modify] [Save] [Cancel] [Close]

Footer: [Add Comments] [Created: 10/9/99 20:03] [DNALIMS]

FIG. 3

Sample Worklists

- Named Sample Collections
- Assignable to Lab Scientists
- Groups Samples for Common Lab Operations
 - Location
 - Check-in/Check-out
 - Lab Procedures

The screenshot shows a 'Worklist' application window with the following components:

- Worklist Name:** PSI SAMPLES
- Assigned To:** DIALIMS
- Created By:** DIALIMS
- Created On:** 10/5/99 13:54
- Modified:** 10/6/99 08:02
- Created:** 10/6/99 17:47
- Buttons:** Modify, Cancel, Save, Save As..., Delete, New, Check In, Check Out, Open Checklist, Print Worklist, Close.
- Containers:** A list of containers with checkboxes. The first container is checked and labeled '# R1'.
- Table:**

Sample Tube ID	Accession #	PPG# Study No	Location
S1	A1	PS1	Fr.1 Comp Shelf Rack
S2	A2	PS1	Fr.1 Comp Shelf Rack
S3	A3	PS1	Fr.1 Comp Shelf Rack
S4	A4	PS1	Fr.1 Comp Shelf Rack
S5	A5	PS1	Fr.1 Comp Shelf Rack
- Footer:**
 - Created:** DIALIMS
 - Modified:** 10/6/99 08:02
 - Created:** 10/7/99 08:50

FIG. 5

- Automates Laboratory Process Tracking
 - Supports Standard Operating Procedures
 - Maintains Uniform Laboratory Processes
 - Records Chain of Custody
 - Tracks Repeat Operations

FIG. 6

FIG. 6

Procedure	Status	SOP Number	SOP Version
DNA Isolation, 3 mL whole blood, Purgene Kit	APPROVED	GEN9709	C
2D6 Allele (A) Identification	APPROVED	CYP2D6A	A
SpecionMax DNA quantitation	APPROVED	MAX9802	A
CYP2C9-3	APPROVED	CYP2C9-3	A
CYP2C9-2 Ver 7	APPROVED	CYP2C9-2	A
CYP2C9-2 Ver 8	APPROVED	CYP2C9-2	A

Print

Save As ...

Procedure Name:

2D6 Allele (A) Identification

Procedure Description:

Laboratory Protocol for Identification of CYP2D6 (A) Allele by RFLP-PCR

Gene:

Allele:

SOP Number:

SOP Version:

Status:

New

Modify

Delete

Save

Cancel

Close

Created

DNALIMS

10/4/99 12:02

Modified

DNALIMS

10/5/99 10:59

FIG. 7

Procedure Steps

- A Single Step in a Lab Procedure
- Multiple Types:
 - Transfer
 - Dilution
 - Concentration Adjustment
 - Sample Preparation
- Highly Customizable
- Plug-in Architecture to Add New Types
- Interfaces to Automation

Procedure Steps

Procedures: DNA Isolation, 3 mL whole blood, Purge Kit

Step	Step Input Type	Batch	Functional Type	Batch
Thaw frozen blood	CheckBox			Batch
Gently mix sample	CheckBox			Batch
Transfer 3 mL of blood to Lysis tube	Transfer			Batch
Add 9 mL of RBC lysis to RBC lysis tube	Functional			Batch
Mix and incubate 10 minutes at room temperature	CheckBox			Batch
Centrifuge 10 minutes at 3000 RPM	Text			Batch
Pour off supernatant into lysis tube	CheckBox			Batch
Resuspend cell pellet by vortexing	CheckBox			Batch
Add 3 mL of Cell Lysis Solution	Functional			Batch
Sample can be stored for 18 months at RT in Cell L	Informational			Batch
STOP PRINT	Informational			Batch

Step: Add 9 mL of RBC lysis to RBC lysis tube

Step Type: C: Informational, C: CheckBox, C: Sample, C: Batch

Parameters:

Volume	9000	200
To final volume	FALSE	
Reagent name	RBC Lysis S	
Reagent prefix	RBC	
Volume optional	TRUE	
Wave scanning	TRUE	
Lock parameters	TRUE	

Created: 10/5/99 09:00 Modified: 9/30/99 14:42

DNALIMS

FIG. 8

Track Changes in Database

- Study
- Lab Procedures
- Sample
- Results

Flexible Audit Reporting Chain of Custody by Accession

FIG. 10

Reporting

- Multiple Report Types
 - Genotype Results
 - DNA Integrity
 - Purification Results
 - Sample Lists
 - Audit Trails
- Flexible Reporting Output Using Excel
- Customized Reporting Using 3rd Party Tools

DNA Purification Results													Sponsor:	Representative:	Investigator(s):	
Study: Test																
Study #: 999-xxx																
Sample #	Storage #	µg/ml	Protocol	Start Vol.	DNA Vol.	Yield	A260	A230	A280	Subject Number	Initial	Date of Birth				
EAI11111	0	Sample test	09/06/00	499	0	0	0	0	0	1:kal		5/31/66				
EAI11112	0	Sample test	02/19/00	48	0	0	0	0	0	2:hb		8/26/7				
EAI11113	0	Sample test	09/06/00	248	0	0	0	0	0	3:lsc		5/22/66				
EAI11114	0	Sample test	09/06/00	248	0	0	0	0	0	4:jmm		4/11/74				
EAI11115	0	Sample test	09/06/00	248	0	0	0	0	0	5:mr		9/9/72				
EAI11117	0	Sample test	09/06/00	248	0	0	0	0	0	1:kal		5/31/66				
EAI11116	0	Sample test	09/06/00	98	0	0	0	0	0	2:hb		8/26/7				
EAI11118	0	Sample test	09/06/00	248	0	0	0	0	0	3:lsc		5/22/66				
EAI11119	0	Sample test	09/06/00	592	0	0	0	0	0	4:jmm		4/11/74				

FIG. 11